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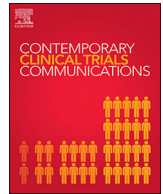
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Incorporating an exercise rehabilitation programme for people with intermittent claudication into an established cardiac rehabilitation service: A protocol for a pilot study

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ABSTRACT

Introduction: Current UK guidance for the treatment of intermittent claudication (IC) states that supervised exercise programmes (SEPs) should be offered as first-line treatment [1], prior to surgical interventions. However, there is currently a national shortage of dedicated SEPs. It has been suggested that the established network of UK Cardiac Rehabilitation (CR) programmes could cater for IC patients. This study will investigate the feasibility of combining IC and CR patients into one SEP, and explore the patient perception's regarding the treatment programme, to establish whether CR could potentially fill the gap in service provision.

Methods and analysis: Patients diagnosed with IC will be incorporated into a CR programme where they will exercise alongside patients with coronary artery disease (CAD). Participants will attend a 2-h class, once a week for a total of 12 weeks. Another group of IC patients will attend an SEP consisting solely of other IC patients (control group).

Outcome measures: The study will evaluate the feasibility of recruitment, retention, and participant experience of the intervention as well as physiological outcomes (primary outcome: pain-free walking, and maximal walking distance; secondary outcomes: physical activity levels, perceived walking ability, and disease-specific quality of life). Outcomes will be assessed at baseline and on completion of the SEP.

Ethics and dissemination: Ethical approval for this study was obtained from North West- Greater Manchester West Research Ethics Committee on 13th June 2018 (IRAS ID: 230391). This study is registered with clinicaltrials.gov (NCT03564080) and conforms to the Declaration of Helsinki. Results will be disseminated via national conferences and published in peer-reviewed journals.

1. Introduction

Peripheral artery disease (PAD) is a progressive disease that occurs as the result of atherosclerotic plaque formation in the major arteries of the leg [2]. The prevalence of PAD in the UK population is 12–14% and it is estimated that 20% of those with a diagnosis of PAD are over 60 [1]. A quarter of patients with PAD experience limiting symptoms that cause physical disability. The main symptom is intermittent claudication (IC), which is categorised as exertional pain or discomfort in the calf, thigh or buttock that is relieved with rest. In 2012, the National Institute for Health and Clinical Excellence (NICE) issued clinical guidance that recommended patients diagnosed with PAD should be offered a programme of exercise rehabilitation as a first line treatment, prior to any surgical intervention [1]. This guidance is supported by a wealth of high quality research over decades showing the positive

impact of exercise therapy on functional capacity and quality of life [3–7]. The non-invasive treatment option of exercise therapy has been shown to be as beneficial as bypass surgery, and more successful than the use of stents, for increasing walking capacity and improving symptom management [8,9]. Exercise therapy is also the more cost effective option, as a 12-week programme would cost approximately £273, while angioplasty would cost £3,867 [10].

The optimal format for exercise therapy is a supervised exercise programme (SEP). These programmes should last for 12 weeks and should be supervised by qualified staff (e.g. exercise physiologists or physiotherapists). Previous research has shown that this format provides better patient outcomes when compared to non-supervised or home-based programmes [11]. Unfortunately, the provision of SEPs in the UK is currently low with only 24% of vascular surgeons having a facility to refer their patients to Ref. [12]. The main barriers reported

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are lack of financial and logistical resources. This poor service provision has massive implications for UK patients, as they do not have access to the optimal, evidence-based intervention. Due to the progression nature of the disease, many patients will therefore go on to need to receive the more invasive and costly revascularisation interventions (angioplasty and bypass surgery). Researchers have proposed that the already established CR rehabilitation services could provide a viable option that would benefit PAD patients [12,13].

The presence of PAD is also a powerful marker of overall cardiovascular risk and preventable cardiovascular deaths. There is a 25–30% increased risk of death within 5 years for those diagnosed with symptomatic PAD, due mainly to myocardial infarction or stroke [14]. This progression can be significantly reduced by aggressively modifying cardiovascular risk factors [15] which is a core component of CR [16,17]. This is further support for CR programmes providing rehabilitation for PAD patients.

Previous research has highlighted an appropriateness of combining different disease populations into one SEP [18]. The study combined heart failure patients with patients with chronic obstructive pulmonary disease who shared similar symptoms (exertional shortness of breath and early onset of fatigue) rather than a shared pathophysiology. CAD and PAD have a shared pathophysiology – atherosclerosis – although the symptoms present in different ways and the limitations on exercise are different. The impact of combining CAD and PAD patients into one group needs to be investigated it is currently unknown whether combined rehabilitation provides additional or in fact less favourable outcomes when compared to stand-alone programmes. This research aims to assess the feasibility of combining the two groups into one rehabilitation setting to provide support for a full-scale RCT.

In clinical settings such as in the NHS, exploring the views and experiences of the service users to gain greater understanding has been shown to improve service provision and subsequently patient uptake [19]. There is a current gap in literature into patient's perceptions and opinions of combined rehabilitation. Indeed, there has been little research to date into the perceptions of PAD patients regarding any form of SEP. This study will therefore utilise a mixed methods design, with qualitative investigation into the experiences of the patients following completion of the SEP (see Fig. 1).

2. Methods

2.1. Study setting

This feasibility study will take place in two SEP rehabilitation departments in two NHS Trusts: Manchester Foundation Trust (MFT) and Salford Royal NHS Foundation Trust (SRFT).

The programme at MFT is a 12-week vascular specific programme, offering exercise and education to PAD patients diagnosed with IC. This site will recruit PAD patients and will act as the control group (referred to as Group 1), as supervised exercise is currently the recommended standard treatment for PAD patients.

The programme at SRFT is a 12-week Cardiovascular Rehabilitation

programme of exercise and education. This site will recruit both PAD and CAD patients for the intervention groups (referred to as Group 2 and Group 3, respectively). Both programmes have been running for over 15 years and follow the recommended guidance for PAD and CR exercise delivery – NICE [1] and BACPR [17] respectively.

Outcomes will be measured at baseline (pre-rehab) and upon completion of the SEP (post-rehab). All patients will be invited to participate in focus groups (post-rehab) in order to investigate their perceptions and experiences of the SEP they attended.

2.2. Ethical approval

As this study involves NHS patients, prior approval was obtained from the North West- Greater Manchester West Research Ethics Committee on 13th June 2018 (IRAS ID: 230391). This study has also been registered with clinicaltrials.gov (NCT03564080) and conforms to the Declaration of Helsinki.

2.3. Study design

There will be 3 arms to this study: a PAD group that is incorporated in to the CR group (intervention arm 1), the CAD group that currently make up the Cardiac Rehabilitation referred patients (intervention arm 2), and the stand-alone PAD group (control arm); (see Fig. 2). In order to generate sufficient data 34 patients will be recruited to each group with an aim to achieve 17 completers from each group. This is due to an expectation of high dropout rate for both PAD and CAD programmes seen at a national level [12,17]. The total recruited will therefore be 102 subjects, to gain 51 completers totally (17 per group).

3. Participants

3.1. Intervention groups

PAD patients (Group 2) will be identified by the vascular specialist teams (surgeons, nurses and podiatrists) and asked if they wish to take part in the study. These participants will be invited to participate in the study during the face-to-face consultation with their specialist, or a telephone consultation. Potential participants will have approximately 2 weeks to consider enrolling in the research study. Participation will be on a voluntary basis. Simultaneously, an age-matched group of CAD patients (Group 3) will be recruited to the combined programme at SRFT to assess the impact of combined SEP on CAD patients. These participants will be identified by the Cardiac Rehabilitation Specialist Nurses at SRFT upon referral to the CR SEP and will have the same 2-week period to decide about enrolling.

The CAD patient's outcome measures of physical fitness and quality of life will be compared to the National Audit of Cardiac Rehabilitation (NACR) as it is outside of the scope of this investigation to have a CAD only control group. Physical fitness will be measured using the incremental shuttle walk test (ISWT) and quality of life using the Hospital anxiety and Depression scale. The NACR data is compiled annually and

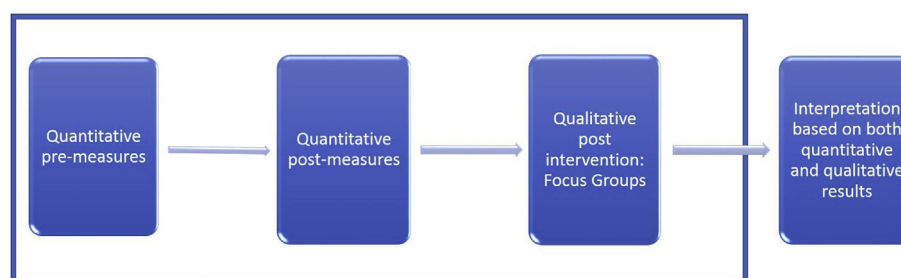


Fig. 1. Mixed methods study design overview.

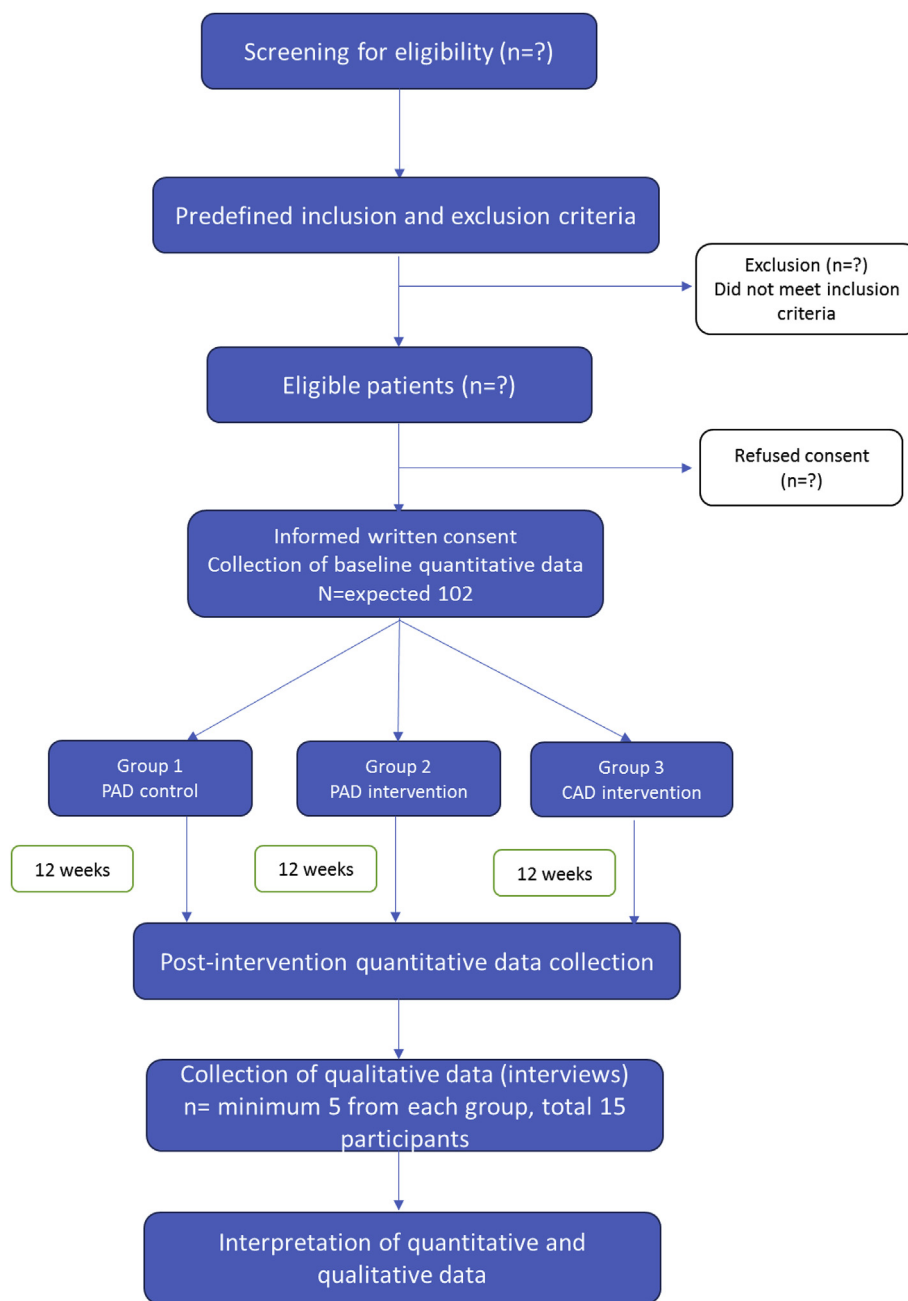


Fig. 2. Flowchart of study. This shows the outline of the 12-week study with the 3 groups involved.

records the national average for these 2 outcome measures. The most recent year's audit results will be used for comparison.

3.2. Control group or “standard care” group

The control group (Group 1) will consist of PAD patients only and will take place at an established SEP at MFT. The use of a SEP has been chosen as the control group or “standard care” group, even though most patients are unable to receive the standard care in the UK. Other research in this area has had an “exercise advice only” group as control [13] however, it has been established that SEPs are better than “exercise advice only” as a treatment option [11]. It has therefore been considered that it would be unethical for some participants to be missing out on the recommended SEP treatment.

3.3. Informed consent

In order to gain informed consent from prospective participants, the content and layout will be described verbally to prospective participants, along with an easy-to-read leaflet/letter with full description of the study (Participant Information Sheet). To avoid any risk of coercion, it will be explicitly stated that they have the right to withdraw from the study at any point, and that no present or future treatment will be affected by enrolling or not enrolling on the study as per Good Clinical Practice guidance [20]. All documents will be available in large print if required.

3.4. Sample size

The sample size of this investigation has been guided by a study by Evans et al. [18], which investigated the suitability of combining two

different patient groups (heart failure and chronic obstructive pulmonary disorder) into one rehabilitation programme. The primary outcome measured by Evans et al. [18], was functional capacity, and a secondary outcome was disease-specific quality of life which matches two of the main outcomes of this proposed study. The sample size from Evans et al. [18], has therefore been used in deciding the sample size for this proposed study. Evans et al. [18], found that 17 participants were required in each group for their outcome measures to reach significance level. Due to the statistically significant findings of Evans et al. [18], using their sample size as guidance will hopefully allow the calculation of the required sample size to power a full RCT from the pilot data.

4. Inclusion and exclusion criteria

4.1. General criteria

As part of this study participants will be required to wear an activity monitor, the activPAL3 (PAL Technologies Ltd, Glasgow, UK), on the first week and last week of the 12-week study. The activity monitor will be kept in place by a medical dressing (e.g. Tegaderm®, PAL Stickie®). People with an existing skin condition such as psoriasis or eczema that would be affected by the application of a medical dressing will be excluded from the study.

All participants will be screened prior to commencing their SEP to ensure they are suitable to take part. The American College of Sports Medicine's Contraindications for Outpatient Cardiac Rehabilitation will be used for this screening process [21].

All participants must be able to start the Graded Treadmill Test (walking speed of 3.2kph, 2mph, 0% gradient). If they are unable to walk at this pace they will be excluded from the study.

All participants must be able to engage in the exercises prescribed in the programme (see Supervised Exercise Programme outline below).

No participant will be excluded due to age or gender.

4.2. Inclusion criteria – PAD patients

All patients recruited will have had a recent diagnosis (0–12 months) of PAD made by either a vascular surgeon, vascular specialist nurse or specialist podiatrist.

4.3. Exclusion criteria – PAD patients

Any patient who has had previous intervention for PAD e.g. balloon angioplasty, stent, bypass or medication, or who have previously completed an SEP will be excluded from the study. This is due to the possibility of previous interventions having an impact on patient perceptions.

Participants who are on vasodilatory medication for PAD (e.g. naftidrofuryl oxalate) will also be excluded from the study as this can increase symptom management and improve functional capacity. Participants who start vasodilatory medication during the study will also be removed.

Any PAD patient who also has a recent diagnosis of CAD (within the past 12 months) or have current symptoms of CAD will be excluded from this study, as the investigation is looking at the specific improvements in PAD, rather than improvement in CAD-related symptom management.

Patients with chronic heart failure (CHF) will be excluded from this study as the focus is comparing CAD with PAD. The presence of CHF will be identified by review of past medical history (e.g. echocardiogram, under care of HF specialist team).

4.4. Inclusion criteria – CAD patients

All patients recruited to the CR group will have had a recent

diagnosis (0–12 months) of CAD (angina, myocardial infarction (MI), or coronary artery bypass graft (CABG). Although HF patients are excluded from the PAD group, patients with HF where ischaemic heart disease is the primary cause (i.e. ischaemic cardiomyopathy) will be included in the study, as the cause of their heart condition is CAD.

4.5. Exclusion criteria – CAD patients

Any CAD patient who has had a previous diagnosis of PAD will be excluded from the study, as their exercise may be limited by PAD symptoms (i.e. intermittent claudication) rather than the cardiac condition. Any improvement in exercise capacity may therefore be confounded by improvements in PAD symptoms [22].

Any participant who has unstable CAD (e.g. unstable angina) will be excluded from the study as this is a contraindication partaking in structured exercise programme [16,23].

5. Initial assessment

All participants will be fully assessed prior to starting their 12-week SEP. This assessment is a standard part of the SEP process where a range of standard clinical measures are recorded (e.g. resting BP, BMI, and waist circumference). This will be conducted by one of the rehabilitation team members. All outcome measures will be taken prior to the patients starting their SEP and repeated upon completion of the programme. A summary of all outcome measures is shown in Table 1.

5.1. Outcome measures

The following items are the outcome measures that will be recorded. The PAD-specific tests have been recommended by the TransAtlantic Inter-Society Consensus (TASC) Working Group for the Management of PAD [2]. The others are standard outcomes measures recommended by the British Association of Cardiovascular Prevention and Rehabilitation (BACPR) [16].

5.1.1. Primary outcome measures

5.1.1.1. Treadmill test. The Gardner-Skinner Protocol [24] will be used during this study to assess walking distance, peak walking speed and functional capacity. The Gardner-Skinner is a standardised graded protocol functional exercise test (FET) that is commonly used

Table 1

This table provides a summary of quantitative outcome measures and the time-point at which they will be recorded.

Quantities subjected to post hoc analysis	
Quantity	Time of measure (weeks)
Demographic	
Sex (M/F)	BL
Age (years)	BL
Clinical	
Blood Pressure (mmHg)	BL, 12 weeks
Resting Heart rate (bpm)	BL, 12 weeks
Height (m), Weight (kg), BMI(kg.m ²)	BL, 12 weeks
Waist circumference (cm)	BL, 12 weeks
Medication	BL, 12 weeks
Physical Functioning	
Graded Treadmill Test (GTT)	BL, 12 weeks
7-day activity monitoring	BL, 12 weeks
Questionnaires	
Vasculol (PAD only group)	BL, 12 weeks
Hospital Anxiety and Depression Scale (HADS)	BL, 12 weeks
Walking Impairment Questionnaires (WIQ)	BL, 12 weeks

BL, Baseline; PAD, peripheral artery disease.

Contraindications for Outpatient Cardiac Rehabilitation	
•	Unstable Angina
•	Uncontrolled hypertension
•	Resting SBP > 180 mmHg and/or resting DBP >110 mmHg
•	Drop in BP >20 mmHg on standing (orthostatic)
•	Uncompensated heart failure
•	Uncontrolled sinus tachycardia (>120 bpm)
•	Significant aortic stenosis
•	Uncontrolled arrhythmias (atrial or ventricular)
•	Severe orthopaedic conditions that would prohibit exercise
•	Acute systemic illness or fever
•	Third-degree AV block without pacemaker
•	Active pericarditis or myocarditis
•	Recent embolism
•	Acute thrombophlebitis
•	Uncontrolled diabetes
•	Other metabolic conditions (e.g. hypokalaemia, hyperkalaemia, hypovolemia) – until adequately treated

Fig. 3. Contraindications for outpatient cardiac rehabilitation - american college of sports medicine [21].

throughout PAD exercise rehabilitation programmes. The treadmill protocol is as follows:

- Treadmill speed is held constant at 2 mph (3.2. kph)
- Treadmill grade begins at 0% and increases 2% every 2 min

For PAD patients, the FET will also establish the initial claudication distance (ICD) and maximal-claudication distance (MWD) using a IC pain scale (Fig. 3). ICD is the point at which initial symptoms of IC are experience (1 out of 4 on the pain scale), and MWD is the point at which the patient can no longer walk (4 out of 4 on the pain scale).

5.1.2. Secondary outcome measures

5.1.2.1. Walking behaviour and physical activity. Walking behaviour and physical activity will be recorded by an activPAL® activity monitor (as used in Clarke et al., 2012) [26] to quantify free-living walking. Data from the activPAL classifies activities into sedentary, standing and stride events. Consecutive stride events are combined to give walking events. The output has been validated for classification of sedentary, upright, standing and walking activities in a range of populations including older adults and patients with IC [25–28]. Baseline activity will be recorded for a 7-day period prior to starting the SEP. During the week prior to completing the SEP, participants will record another 7-day period of activity. The outcome data recorded will include steps per day, step cadence, and sedentary time.

The activPAL® will be attached to the front of the thigh using a medical grade waterproof dressing. It weighs 15 g.

5.1.3. Quality of life measures

5.1.3.1. Hospital anxiety and depression scale (HADS) questionnaire. This is a 14-item questionnaire with 7 questions measuring anxiety and 7 questions measuring depression levels. This is a commonly used in clinical settings and is a standard questionnaire used in Cardiac Rehab departments [16,23,29]. It takes on average 5 min to complete this questionnaire, and will be completed by the participant on their own.

5.1.3.2. King's college vascular quality of life (Vascu-QoL) questionnaire (PAD-specific). This is a 25-item disease-specific quality of life questionnaire that has 5 domains (pain, symptoms, activities, social and emotional) and has been widely used in PAD research [30,31]. Disease-specific quality of life measures are recommended by TASC (2007) [2] in combination with generic questionnaires (such as HADs)

as they are more sensitive to change in specific symptoms that are related to the condition. This questionnaire takes on average 10 min to complete, and will be completed by the participant on their own.

5.1.3.3. Walking impairment questionnaire (WIQ). This is a PAD disease-specific questionnaire assessing the perceived impact of claudication symptoms on the individual being measured. This is a commonly used questionnaire in PAD research since its development by Regensteiner et al. [32], and is recommended by TASC (2007) [2] to assess patient perceived symptoms. It takes on average 5 min to complete and will be completed as part of the initial assessment.

5.2. Supervised exercise programme outline

5.2.1. The programme

Patients from all groups will attend a 2-h session once a week, for 12-weeks. This will involve a 1-h supervised exercise session, followed by an education session. Each session will start with a pre-screening interview to confirm suitability to exercise that day. The exercise will start with a warm up period lasting 5–10 min for PAD patient, and 10–15 min for CAD participants. The prolonged warm up period for participants with CAD is required to comply with national guidance [23], due to the risk of developing warm up angina in this population. This will be followed by a 20–30 min conditioning phase, and a 10-min cool-down. Each participant will have to successfully complete at least 8 of the 12 sessions for the programme to be considered as being completed.

5.2.1.1. PAD specific exercise. The conditioning phase for the PADs patients at both hospital programmes will involve completion of a circuit of exercises designed to bring on claudication within 3–4 min. Participants are encouraged to exercise to near-maximal claudication pain, and then rest until the pain has subsided before starting the next exercise. Participants will use the 0–4 scale to rate the claudication pain experienced during exercise (Fig. 4), with the aim of reaching 3 to 4 on the scale before starting the rest period. Rehabilitation staff will also monitor participants heart rate using Polar® FT2 heart rate monitors (Polar Electro, Kempele, Finland) to ensure that they do not exceed 80% heart rate reserve. This is accordance with the AACVPR [33] and NICE [1] recommendations and will ensure safe and effective exercise. The exercises included in the circuit are:

- Treadmill walking
- Heel raises
- Trampette walking/jogging
- Sit to stands
- Toe-walking
- Step ups

5.2.1.2. CAD specific exercise. The conditioning phase for CAD patients will consist of the same circuit of cardiovascular exercises as the PAD

Intermittent Claudication Rating Scale	
0	No claudication pain
1	Initial, minimal pain
2	Moderate, bothersome pain
3	Intense pain
4	Maximal pain, cannot continue

Fig. 4. This shows the Intermittent Claudication Rating Scale which will be used by patients to grade the amount of claudication pain they experience during the GTT and SEP. Taken from ACCVPR Guidelines for Cardiac Rehabilitation and Secondary Prevention Programs (2013).

Table 2

This table outlines the steps taken in the thematic analysis of the focus group data. Taken from: Braun & Clarke, (2006) Using thematic analysis in psychology. *Qualitative Research in Psychology*. 3: pp77-101.

Phase	Description of the process
1. Familiarizing yourself with your data:	Transcribing data (if necessary), reading and re-reading the data, noting down initial ideas.
2. Generating initial codes:	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. Searching for themes:	Collating codes into potential themes, gathering all data relevant to each potential theme.
4. Reviewing themes:	Checking if the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic 'map' of the analysis.
5. Defining and naming themes:	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme.
6. Producing the report:	The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing a scholarly report of the analysis.

group, however this group will exercise symptom-free (i.e. without chest pain or discomfort). Participants will be given an initial exercise prescription which details the amount of time spent on the cardiovascular exercise (ranging from 1 to 5 min), which is followed by 1 min of active recovery (marching on the spot with performing a light resistance exercise e.g. biceps curl). During this interval-based exercise circuit, CAD patients will be closely monitored by staff using Polar® FT2 heart rate monitors (Polar Electro, Kempele, Finland) to ensure patients do not exceed their individually prescribed heart rate ranges (between 40 and 70% heart rate reserve). The 6–20 Rating of Perceived Exertion (RPE) scale [34] will also be used to ensure safe and effect exercise throughout. This complies with the standard cardiac rehabilitation programme exercise guidance set by the BACPR [16] and Association of Chartered Physiotherapist working in Cardiac Rehabilitation (ACPICR) [23].

5.2.1.2.1. Physical activity and exercise advice. As participants attend each exercise programme only once a week, the rehabilitation team will provide guidance and encouragement for patients to keep active outside of the sessions. Patients will be given pedometers to use and weekly activity goals will be set and reviewed each week by a member of the rehabilitation team to assess progression. These goals will be individualised to each patient so that they are progressive and achievable. An example of a goal could be increasing daily step count by 500 steps.

5.2.1.2.2. Patient education. Following each of the 12 exercise sessions, all patients will be invited to attend education sessions. The sessions are based on the clinical guidance from NICE [1] recommending patients are educated on the importance of lifestyle interventions including:

- aggressive lipid modification and statin therapy
- smoking cessation
- diet, weight management and exercise
- the prevention, diagnosis and management of diabetes
- the prevention, diagnosis and management of high blood pressure
- antiplatelet therapy

6. Qualitative post-intervention study

Upon completion of the 12-week supervised exercise programme, participants will be invited to attend focus groups to explore their thoughts and concerns about the intervention (Fig. 1). Themes will be constructed from the data to give insight into the experiences of the different participant groups. As participation is important for rehabilitation departments, it is essential to include the participants' perspective in the evaluation of the treatment programme.

6.1. Data analysis

6.1.1. Quantitative data

The primary outcome data of pain-free and maximal walking

distances will be tested for normal distribution. Statistical analysis software (IBM SPSS Statistics 24®) will then be used to assess for significant differences between the groups pre and post-treatment. Within groups and between group differences in exercise capacity will be analysed using a factorial ANOVA to compare the difference in the levels of improvement between groups. Wilcoxon tests will be used to analyse within group differences in the quality of life questionnaire data. Between group differences will be analysed using Mann-Whitney tests.

The CAD group will also be compared to the National Audit of Cardiac Rehabilitation (NACR) data to assess the impact on the CAD group performance against expected national levels (physical fitness and quality of life).

The effect sizes will be calculated using the Cohen's *d* so that the results can be compared to other studies.

6.1.2. Qualitative data

The analysis will be influenced by Braun & Clarke's [35] six phases of thematic analysis as described in Table 2.

The results of both the quantitative data analysis and the thematic analysis from the focus groups will then be used to draw conclusions about the effectiveness of the treatment options.

6.1.2.1. Dissemination and impact. Upon completion the study results will be published in peer-reviewed journals and presented at national conferences and to patient groups.

Conflicts of interest

None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.conctc.2019.100389>.

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